REVISED USDOT DRUG & ALCOHOL TESTING REGULATION: 49 CFR PART 40

This document will provide a brief but comprehensive summary of the 2023 final revisions to 49 CFR Part 40. This document will discuss how these revisions may impact you and your drug & alcohol testing program. This document will also discuss any action items which you may need to take to ensure ongoing compliance with 49 CFR Part 40.

OVERVIEW

On February 28, 2022, the USDOT issued a Notice of Proposed Rulemaking (NPRM) for 49 CFR Part 40.

- 49 CFR Part 40 is the regulation that mandates drug and alcohol testing for the United States Department of Transportation (USDOT) and USDOT Agencies (i.e., FTA, FMCSA, FAA, etc.).

On May 02, 2023, the USDOT published a final rule with all final revisions to 49 CFR Part 40.

- The final rule can be accessed on the USDOT – Office of Drug and Alcohol Policy and Compliance's (ODAPC) website: https://www.transportation.gov/odapc/frpubs

The newly revised version of 49 CFR Part 40 will become effective on June 1, 2023

After reviewing this document, please feel free to contact your State DOT and/or RLS & Associates, Inc. (RLS) with any questions.

Table of Contents

SUMMARY OF CHANGES

On May 2, 2023, the Department of Transportation (DOT) published a final rule in the Federal Register (88 FR 27596).

This final rule, among other items, amends the DOT's regulated industry drug testing program to include oral fluid drug testing.

WHEN DOES THE NEW RULE GO INTO EFFECT?

- The final rule is effective June 1, 2023

CAN I START CONDUCTING DOT-REGULATED ORAL FLUID DRUG TESTS?

- No. Not yet!
  - The conduct of DOT-regulated oral fluid drug tests will not be permitted until DHHS certifies at least two (2) laboratories for specimen testing
    - One lab will be the primary lab
    - The second lab will serve as the split specimen laboratory (when needed).
  - As of the time of the publication of this document (05/07/2023), DHHS has not yet certified two laboratories.

- Are you REQUIRED to start conducting oral fluid drug tests?
  - No.
  - Urine drug testing will still be permitted. DOT is not requiring the use of oral fluid specimens for drug tests (with a very limited exception, see Pages 4 and 9). The final rule is simply allowing oral fluid testing as an option, once available.

WHAT ELSE WAS UPDATED?

The allowance of oral fluid specimens for drug testing wasn't the only change that occurred within this new final rule.

Other major updates are summarized in TABLE 1 (on the following page)

[SPACE LEFT BLANK INTENTIONALLY]

TABLE 1 – WHAT ELSE WAS UPDATED?

Topic Area	Summary of Changes	Special Notes
Use of ID numbers other than Social Security Numbers (SSNs) or Employee ID Numbers (EINs)	In addition to SSNs and EINs, the new rule will also allow the use of: 1. State-issued identification card numbers; 2. State-issued driver's license numbers (including CDL numbers); 3. Any other state-issued or federally-issued identification number.	For tests being conducted under the authority of FMCSA, the ID number used is required to be the CDL number and the State of Issuance Code.
Substance Abuse Professional (SAP) Evaluations	SAPs will be allowed to conduct evaluations either in-person or remotely. • But only if the SAP's qualifying credential authorizes them to do remote evaluations. The choice between in-person vs remote evaluations will be the decision of the SAP If done remotely, the technology used for the evaluation must: • Permit real-time two-way audio and visual interaction between SAP and employee; • Have sufficient quality (i.e., speed of internet, clarity of display), to allow the SAP to gather all visual/audible info the SAP would normally observe face-to-face; • Have sufficient robust security to protect confidentiality; • Only be utilized if the SAP's qualifying credential authorizes them to do so. SAPs must abide be the geographic limitations applicable to their credential(s) when performing remote evaluations. • SAPs must not conduct an evaluation that exceeds their geographic limitations under their credential(s).	If an SAP conducts an evaluation outside of the geographic jurisdiction of their credential: • The employee will not be required to seek the evaluation of a second SAP. • The evaluation and assessment of the SAP is still valid, even if the SAP exceeds their geographic jurisdiction. • The employer is permitted to utilize such evaluations and follow-up plans if they choose to return the employee to safety-sensitive work. If an SAP chooses to run operations from their home, they must furnish that address on their letterhead. • If using one's home address is not acceptable to an individual SAP, they must continue to provide a physical commercial location address for Part 40 purposes. • SAPs are still NOT permitted to only have a PO Box address. 49 CFR Part 40 requires the SAP to have a physical address and location where DOT can inspect, audit, or investigate an SAP and their records.

Topic Area	Summary of Changes	Special Notes
Medical Review Officer (MRO) Updates	1) Reversal of Cancelled Test Results • MROs will be permitted to reverse a cancelled test result in situations where the test was cancelled due to paperwork errors (which would otherwise have been correctable flaws) which were not corrected before the MRO sent the cancellation to the employer. • The administrative paperwork errors that can be reversed include those listed in 40.203 and 40.205 2) Verifications of Prescriptions w/ Pharmacies • MRO staff are now permitted to contact pharmacies to authenticate whether or not the prescription offered by the donor is authentic. 3) MRO Training for Oral Fluid Drug Tests • MROs are NOT required to undergo recertification training due to the addition of oral fluid specimen testing. • DOT strongly suggests that MROs seek supplemental information about oral fluid testing prior to the time HHS certifies two labs for testing.	Medical Evaluations for Shy Bladder/Dry Mouth • If a donor is unable to provide a sufficient oral fluid specimen after an insufficient urine specimen (or vice a versa), the donor would only be required to have a referral physician evaluation for the 2nd specimen type attempted.
Directly Observed Collections	When a directly observed collection is required (see Part 40.67), either a directly observed urine collection or oral fluid collection will suffice. In a circumstance when an employee is required to undergo a directly observed collection (See Part 40.67) and the collection started as a urine specimen collection, **if the same gender observer cannot be found:** • If the employer has a standing order in place to allow oral fluid testing in such situations, the collector may follow that order. ○ The collector does not have to be the same gender as the donor in the case of an oral fluid collection.	In a circumstance when an employee is required to undergo a directly observed collection (See Part 40.67), if the donor is a transgender or nonbinary individual, an oral fluid collection MUST be conducted. • Oral fluid testing is now the ONLY acceptable method by which to conduct a directly observed collection on an individual who is transgender or nonbinary.

Topic Area	Summary of Changes	Special Notes

	• If the employer does NOT have a standing order, the collector must contact the DER and either:
	  ○ Conduct an oral fluid test if the collection site is able to do so.; or
	  ○ Send the employee to a collection site acceptable to the employer for the oral fluid test.	

Changes to Definitions and Appendixes	The updates to 49 CFR Part 40 include many revisions to the definitions listed as well as the appendixes.	17 definitions have been modified in 49 CFR Part 40.3. • For the most part, the changes are not substantive
DOT Agency Regulation Amendments	The new final rule (49 CFR Part 40) also amends the applicable D&A regulations for the following USDOT-Agencies: • FTA • FAA • FMCSA • FRA	These amendments were made to ensure consistency within the DOT by: • Removing or adjusting references to the word "urine" • Adding references to oral fluid • Removing/amending some definitions for conformity • Other miscellaneous technical changes or corrections

[SPACE LEFT BLANK INTENTIONALLY]

WHAT DOES THIS MEAN FOR … ME?

The summary of changes presented in the preceding pages provide an overview of the 05/02/2023 major updates to 49 CFR Part 40. The sections below try to clarify what these changes mean to the major stakeholders in your USDOT-FTA drug and alcohol testing program.

WHAT DOES THIS MEAN FOR … EMPLOYERS?

- The decision on WHICH specimen type (i.e., Urine or Oral Fluid) will be utilized for drug testing is the choice of the EMPLOYER – not the employee
    - The EMPLOYER chooses the collection methodology for each test reason
        - For example, an employer could have a policy that all random tests will start with a urine specimen collection, while all post-accident, reasonable suspicion, return-to-duty, and follow-up tests will start with an oral fluid collection, etc.

    - The EMPLOYER chooses the collection methodology for any subsequent collection following a shy-bladder, dry mouth, or other test that requires a directly observed collection.

    - It is a BEST PRACTICE to have a standing order in place with your collection site(s):
        - This will be the "guiding document/direction" to your collection site(s) so they know what kind of collection you want performed (i.e., oral fluid vs urine) for each testing circumstance.

- All oral fluid collections are considered directly observed collections
    - DOT recognizes that directly observed specimen collections have long been the most effective method for preventing donors from cheating.

    - Directly observed URINE collections are only permitted in certain circumstances due to the donor privacy concerns.

    - However, oral fluid collections are not restricted to those same specific circumstances.
        - Unlike directly observed URINE collections, an oral fluid collection is much less intrusive on the tested donor's privacy.

        - Having the flexibility of both options allows an employer the ability to perform directly observed collections as an oral fluid test without concerns about the gender of the observer.

- Designated Employer Representatives (DERs) must still remain available to collectors at all times.
    - This has ALWAYS been the case, but it is now more important than ever.

    - DERs must be available to discuss problem collections and standing orders on what type of test the employer wants in problem collection scenarios.
        - Such as if an employee does not provide a sufficient urine specimen, does the employer want the collector to switch to an oral fluid collection?

WHAT DOES THIS MEAN FOR … EMPLOYER DRUG & ALCOHOL TESTING POLICY?

- FTA has stated there is no need for employers to make any changes to their D&A testing policies unless the policy specifically refers to "urine" as the only specimen authorized for drug testing
    - If that is the case, the policy needs to be updated to read "urine and/or oral fluid"

- If an employer is going to authorize oral fluid testing, the policy will need to:
    - State the testing events for which an oral fluid collection will occur (e.g., pre-employment, random, etc.).

    - State if oral fluid collections will be authorized for shy bladder situations and directly observed collections.

WHAT DOES THIS MEAN FOR … EMPLOYEES?

- Employees could be subject to either an oral fluid collection or a urine collection for any DOT-regulated test.
    - The choice of whether to conduct an oral fluid or a urine test is up to the EMPLOYER.

- In circumstances when a second collection is needed during a testing event.
    - e.g., initial temperature of urine specimen is out of range, or insufficient quantity for either oral fluid or urine, etc.

    - The employer may choose to change to the other specimen type of collection to finish the testing event.

- SAP evaluations may be conducted remotely.

[SPACE LEFT BLANK INTENTIONALLY]

WHAT DOES THIS MEAN FOR … COLLECTORS?

- Collectors (and collection sites) must know the employer's preferences and standing orders for regular and problem collections.

- Employee ID on the CCF can be any of the following:
  - SSN
  - Unique identifier issued by the employer to the employee
  - State-issued identification card number
  - State-issued driver's license number (including a CDL number)
  - Any other state or federally-issued identification number
    - For tests regulated by FMCSA - Must be CDL number and State Code

- Since either urine or an oral fluid collection may be required:
  - Ensure that either you or a coworker is qualified to collect either specimen type.

  - If no one is qualified to conduct the alternate collection, contact the DER so the employer can make arrangements to have the employee tested at another collection site.

- Oral Fluid Collectors must:
  - Obtain training to proficiency in the operation of the particular oral fluid collection device you will be using.
    - If you will be using more than one, you need to prove initial proficiency on each device.
  - Ensure that you complete the correct line on Step 2 of the CCF – ORAL FLUID.
  - Check the expiration date on the device or the package and show it to the employee.
  - Not use the device after its expiration date.
    - This would be a "fatal flaw"
  - Check "each device within expiration date?" in Step 2 of the CCF after ensuring the device is within its expiration date.
  - Enter the "Split Specimen Device Expiration Date" in Step 4 (Copy 1) of the CCF.
  - Use a new CCF when switching from one collection methodology to another (urine to oral fluid, or vice a versa).
    - You must also document the reason for the change in the remarks section of the CCF.

[SPACE LEFT BLANK INTENTIONALLY]

WHAT DOES THIS MEAN FOR … C/TPAS?

- As a Consortium/Third Party Administrator (C/TPA), if you are administering a program for an employer, you must:
  - Know the employer's decision about the testing methodologies to be used in each testing circumstance.
  - Make sure there are agreements in place for both oral fluid and urine collections and laboratory testing.
    - Remember, while an employer may opt for only one methodology, oral fluid testing must be available for directly observed collections for transgender and nonbinary individuals.

- A best-practice will be to establish "standing orders" for each employer.
  - These would be shared with the collectors so everyone is aware of what specimen they need to collect for regular collections, directly observed collections, and other circumstances (such as shy bladder and dry mouth scenarios).

WHAT DOES THIS MEAN FOR … LABS?

- For oral fluid collections:
  - If you receive an expired device, you must reject it from testing.
  - If the collector fails to enter the expiration date, or it was entered incorrectly, in Step 4 of the CCF, you must reject the specimen for testing, UNLESS:
    - The lab is able to determine expiration date by inspecting bottles A and B.
    - In which case the lab will note the correct date and proceed with the testing process.

- Labs must provide data to USDOT bi-annually that is categorized by:
  - DOT operating administration (FRA, FTA, FAA, PHMSA, FMCSA)
  - Test reason (pre-employment, random, return-to-duty, follow-up, post-accident, reasonable suspicion/cause)
  - Specimen type (urine or oral fluid)

EDUCATION

EMPLOYEE EDUCATION

As a best-practice, your agency should consider conducting some form of employee education about the changes to the regulation. This training will help ensure the employees understand the changes and the potential impacts of the revised regulation. This document could be used as an outline to assist you in providing a brief training.

Furthermore, USDOT-ODAPC has provided a "summary of changes" on their website, which includes a paragraph for employees: https://www.transportation.gov/odapc/Notice_Summary_May_2023

SERVICE AGENT EDUCATION

As a best-practice, you should contact your collection site(s), MRO(s), SAP(s), and C/TPAs to ensure they are aware of the revised regulations, as well as the areas of the new regulation which pertain specifically to their responsibilities.

- ODAPC Summary of Changes:
  - https://www.transportation.gov/odapc/Notice_Summary_May_2023
  - https://www.transportation.gov/odapc/Notice_CCF_May_2023

- Published Final Rule:
  https://www.transportation.gov/odapc/frpubs

EXHIBIT A – PART 40 REDESIGNATION TABLE

As an effect of publishing this updated version of 49 CFR Part 40, DOT is redesignating (i.e., renumbering and reordering) numerous sections of Part 40 to provide a more easily followed flow for users.

REDESIGNATIONS OF SECTIONS IN PART 40	
Old Section	New Section
40.35	40.36
40.41	40.42
40.45	40.40
40.47	40.41
40.49	40.44
40.51	40.45
40.73	40.79
40.85	40.82
40.87	40.85
40.89	40.86
40.91	40.87
40.93	40.88
40.95	40.89
40.96	40.90
40.99	40.84
Appendix B	Appendix D
Appendix C	Appendix E
Appendix D	Appendix F
Appendix E	Appendix G
Appendix F	Appendix H
Appendix G	Appendix I
Appendix H	Appendix J